particular generic claim is allowed, Applicants will identify which species fall under such allowed claim. Then, as was indicated by the Applicants in the "Election and Amendment" paper of December 21, 2000, upon the allowance of a generic claim, Applicants will be entitled to consideration of the relevant claims to additional species as provided by 37 CFR 1.141.

With respect to claims 75 and 76, the Examiner wants to withdraw them as dependent on non-elected claim 71. Claims 75 and 76 correspond to elected claims 17 and 20 and cover an embodiment with two auxiliary lumens which is part of the elected species. Therefore, Applicants amended claims 75 and 76 to make them dependent from the elected claim 60 and, as amended, these claims are believed to be properly pending and should not be withdrawn.

The Examiner objects to the drawings, or claims 26 and 79, as not showing a claimed feature. In response, Applicants have added FIG. 11D as indicated on the attached drawing sheet and also modified the specification accordingly. The claims are now depicted, and no new matter has been added. Applicants respectfully request that the Examiner indicates its acceptance of FIG. 11D so that Applicants could forward formal amended sheet 7 with FIG. 11D to the Drafting Branch at an appropriate time, as stated in 37 C.F.R. § 1.85(c).

The Examiner has objected to the specification as being nonenabling with regard to "the connection of the junction housing in relation to the outer tube and lumens therein." The Examiner suggested that clarifying confusion between the distal and proximal end locations would results in the Examiner withdrawing this rejection. The objection apparently stems from the Examiner's understanding of the language used in claims 7, 10, 67, and 70 describing the relationship between the main channel, device channel, junction housing, and outer tube. That language has been clarified as shown in the amended claims and so the issue of enablement of the specification is believed obviated. Moreover, the Applicants amended a description in the specification on page 13 line 7 (with reference to Figs. 1 and 4) to correct an inadvertent error by replacing "the **proximal** end of the outer tube 12" with "the **distal** end of the outer tube 12" (emphasis added). Applicants respectfully assert that the specification, including drawings, clearly enables the numerous disclosed embodiments, and in particular the junction housing and tube/sheath connection. If there is some other reason for this objection, the Examiner is encouraged to contact the undersigned.

The plurality of claim rejections under 35 USC §112, second paragraph, have been addressed with the claim changes noted in the appendix, as reflected in the retyped claims above. Most of the proposed changes are either directly respond to the Examiner's suggestion or self-

explanatory. The Applicants, however, would like to particularly address several of the Examiner's rejections as follows.

The Examiner rejected claim 6 as indefinite in light of the "adjacent the proximal end of the device lumen" language in claim 5. Since the above language was deleted from claim 5, no further amendment of claim 6 is believed necessary. Also, it is believed that "the device lumen valve" of claim 6 has proper antecedent basis in line 3 as it refers to the device lumen valve of claim 5 from which it depends. Similarly, no amendments are necessary to claim 66.

With respect to the rejection of claims 8, 32 and 68, it is respectfully submitted that those claims are clear as written. These claims do not state that "the material of the junction housing" is "more rigid that the junction housing." Instead, they state that the device lumen valve is molded separately of a material more rigid than the junction housing and is assembled by insertion in a cavity formed in the junction housing. In light of the above, no amendments are necessary to claims 8, 32 and 68.

Claim 9 also is definite as written since "the device lumen valve" in lines 3-4 has an antecedent basis: It refers to the device lumen valve already introduced in claim 5 from which it indirectly depends through claim 8.

To correct lack of proper antecedent basis in claim 20, instead of amending claim 20, claim 17 (from which claim 20 depends) was amended accordingly.

In light of the amendment of claim 1, claims 28 and 29 do not require any amendment since "the flexible wall" and "the auxiliary lumen" now have proper antecedent basis. Similarly, in light of the amendment of claim 60, "the auxiliary lumen" of claim 61 has a proper antecedent basis.

If the intent of any of the changes is not clear, or if there is any other issue with respect to the indefiniteness of the claims, the Examiner is encouraged to contact the undersigned.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE.**" All amendments are fully supported by the specification and no new matter has been introduced.

Discussion of Palestrant

Claims 1-7, 17, 21-24, 26-29, 30-33, 37, 60-67, 69-70, and 77-79 stand rejected under 35 USC §102(b) as being anticipated by Palestrant (USPN 5,472,418). Palestrant discloses a

collapsible vascular catheter having two or more flattened strips of flexible material attached along their side edges. Figs. 11 and 12 show three and four such strips to form completely collapsible catheter having, respectively, two and three lumens.

In contrast, the present invention provides for a combination device possessing the features of both introducer and multiple lumen catheter. Moreover, the device of the present invention, contrary to the teachings of Palestrant, is not intended to be completely collapsible. Independent claims 1 and 60 provide an outer tube or elongated body that defines at a particular location along its length a cross-sectional area that remains substantially unchanged, as well as an internal flexible wall (or walls) defining variably sized device and auxiliary lumens. (The "particular location" term is intended to clarify that though the overall cross-section of the tube may change along its length, as in a tapered embodiment of a catheter described on page 11 lines 14-16 of the specification, the relationship of the outer tube and inner lumens is as specified in the claim at any particular axial location). Therefore, since the cross-sectional area of the outer tube or elongated body remains substantially unchanged, that cross-sectional area at all times provides a maximum cross-section which limits expansion of the device lumen (or the auxiliary lumen) defined therein. The term "substantially unchanged" is intended to include some minor changes in the cross-section of the outer tube due to the natural flexibility or stretching of the material of the outer tube (as described on page 17, lines 3-14).

The "outer tube" of Palestrant, quite to the contrary, is completely collapsible and as such it does not have a cross-sectional area which remains substantially unchanged. The catheter of Palestrant in its collapsed state can be expanded by the inner lumen(s) (i.e., the cross-sectional area of the outer tube when collapsed will not limit the size of the device lumen, or any other inner lumens). As an added benefit, there is no need to "inflate" the outer tube, as in the catheter of Palestrant, when expanding the device lumen of the present invention.

To summarize, the effective size of any one of the inner lumens of the multiple lumen access device of the present invention could be expanded by decreasing the effective size of the other lumens that are not being used at the time without the need to sacrifice the overall size of the access device. Therefore, at least for the reasons discussed above, claims 1 and 60 are believed novel and nonobvious over Palestrant. Claims 2-7, 17, 21-24, 26-29, 61-67, 69-70 and 75-79 are also patentable over Palestrant at least for the reason that they depend from the allowable claims 1 and 60.

Claim 30 provides a multiple lumen sheath and a soft junction housing connected to the proximal end of the sheath, the junction housing having certain internal channels and a cavity. Palestrant discloses a catheter with a "[t]railing end 24 [that] terminates in a conventional **rigid** plastic body 26 having a knurled collar or hub 28 to facilitate handling" (col. 6, lines 29-31, emphasis added). In fact, Palestrant teaches away from the claimed invention by providing a rigid and conventional for catheters plastic body 26, rather than a soft junction housing on a multiple lumen access device, as claimed. At least for the reason described above, claim 30 and all of its dependent claims are also believed novel and nonobvious over Palestrant.

Discussion of Young

Claims 1-3, 17-18, 20-24, 26, 28-30, 37, 60, 62, and 77-79 stand rejected under 35 USC §102(b) as being anticipated by Young (USPN 5,451,206). Young discloses a triple lumen catheter having coextruded outer (58) and inner (60) layers, with the inner layer forming a septum 22 dividing the inner lumen of the catheter into multiple lumens. Young completely fails to teach a flexible wall as required by the independent claims 1 and 60. At several places Young teaches coextruded materials that "reduce the likelihood of septum deflection during use" (col. 9, lines 54-63, and col. 10, lines 15-18). Therefore, Young does not disclose or suggests, and in fact teaches away from, the flexible wall as in claims 1 and 60.

With respect to the independent claim 30 and its dependent claims, these claims are also allowable in light of Young. Young simply teaches that the proximal end of the catheter has a "Y-shaped connector hub 16" typical for the infusion catheters. Moreover, Young stresses on page 7 lines 31-34 that its invention is intended also for single lumen catheters. Since Young is not directed to a multiple lumen access device, it is not concerned with and does not disclose features attributable to an access device combining functions of an introducer and a multiple lumen catheter. There is no mention of a device lumen, or soft junction housing, or internal channels/cavity as claimed. Therefore, all of the claims are believed novel and nonobvious over Young.

Discussion of Palestrant and Nishijima

Claims 8-10 and 34-36 stand rejected under 35 USC §103(a) as being obvious over Palestrant in view of Nishijima, et al. (USPN 5,092,846). Applicants respectfully assert that Palestrant fails to teach or even suggest features required by the independent claims 1 and 30, and

therefore required by its dependent claims 8-10 and 34-36 (see the discussion above with respect to Palestrant). Since Nishijima does not disclose or suggest these features either and was admittedly cited by the Examiner only for its disclosure of "a valve device in the analogous art of medical introducers," the combination of Palestrant with Nishijima, et al. is insufficient to teach the present invention. Either alone or in combination, these references fail to teach the invention as claimed. Moreover, Nishijima, et al. discloses a conventional introducer valve for medical devices, but fails to teach the particular device valve as presently claimed. For example, there is no disclosure of a soft junction housing and a relatively more rigid device valve that fits in a cavity therein. In light of the above, Applicants believe the §103(a) rejection is obviated.

In view of the above amendments and remarks, Applicants believe that the pending claims are in condition for allowance. If any further questions or issues arise that could be resolved over the telephone, the Examiner is encouraged to contact the undersigned attorney to schedule a teleconference.

Dated: August 22, 2001

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE DRAWINGS:

In the drawing sheet (No. 7), an additional FIG. 11D has been added to the original sheet containing only FIG. 11C.

IN THE SPECIFICATION:

On page 7, after line 29, the following paragraph has been added:

-- FIG. 11D is a sectional view of an alternative multiple lumen access device having flexible walls made of a material different from the material of the outer tube of the multiple lumen access device.--

On page 13, the first full paragraph has been amended as follows:

An opening 72 (*see* FIG. 1 and FIG. 5) is provided towards the distal end of outer tube 12. The opening 72 is provided to allow exit of fluid from auxiliary lumen 48 which has been introduced through infusion tube 58. Likewise, an opening 74 (shown in phantom in FIG. 1 and also shown in FIG. 4) is provided for allowing the fluid introduced through infusion tube 60 to exit auxiliary lumen 36 at the [proximal] distal end of the outer tube 12.

On page 21, the second full paragraph has been amended as follows:

As described previously in regards to the exemplary embodiment illustrated in FIGS. 1-5, the outer wall 15 of the embodiment illustrated in FIGS. 11A-11C is preferably made from any of the well-known polymer materials used in fabricating introducers and other access devices. Preferably, the material used and wall thickness for the outer wall 15 are such that the outer wall 15 is a relatively stiff tube in relation to the inner walls 25 in the radial direction. Further, the material used for the outer wall 15 should be compatible for molding purposes with the material used to form the inner walls 25. It is preferred that the entire cross-section of the multi-lumen portion of the device 10, including the outer tube 12 and inner walls 25, is extruded together from a homogeneous material. Alternatively, the outer wall 15 and inner walls 25 may be coextruded and the junctions 27 be formed by molding of the inner 25 and outer wall 15 together during the

coextrusion process, as seen in FIG. 11D. Therefore, outer wall 15 and inner walls 25 may be made from the same material or different materials, as shown in FIG. 11D. The inner wall 25 is preferably made from softer versions of the various polymers listed previously. When using different materials, the materials should be compatible for bonding or fusing together.

IN THE CLAIMS:

1. (Amended) A multiple lumen access system for use in providing an entry port into the human body for selectively introducing medical devices therethrough and for providing auxiliary access into the body, the system including a multiple lumen access device comprising:

an outer tube which has a distal end for introduction into the body and a proximal end, the outer tube at a particular location along its length having a cross-sectional area which remains substantially unchanged;

a device lumen defined within the outer tube, the device lumen having a distal end and a proximal end, wherein medical devices may be passed through the device lumen;

[at least one] an auxiliary lumen defined within the outer tube and separately from the device lumen, the auxiliary lumen having a distal end and a proximal end;

[at least one] a flexible wall located within the outer tube having a distal end and a proximal end and opposite sides, wherein one side of the wall partly defines the device lumen and the other side of the wall partly defines the auxiliary lumen, the wall being sufficiently flexible to be movable from a [relaxed] first position, where[in] the device lumen at the particular location has a first cross-sectional area, to multiple flexed positions, where[in] the device lumen at the particular location has corresponding multiple cross-sectional areas which are greater than or less than the first cross-sectional area of the device lumen, and wherein at the particular location any of the cross-sectional areas of the device lumen does not exceed [less than] the cross-sectional area of the outer tube.

3. (Amended) The multiple lumen access system of claim 1 further comprising [one or more] a fluid reservoir[s] connected to [one or more of] the proximal end[s] of the auxiliary lumen[s].

4. (Amended) The multiple lumen access system of claim 1 further comprising a junction housing having a proximal end and a distal end to which the proximal end of the outer tube connects, the junction housing including a main channel in fluid communication with the device lumen and [at least one] an auxiliary channel in fluid communication with the [at least one] auxiliary lumen, the main channel and auxiliary channel diverging from each other [the outer tube] to be non-intersecting in the junction housing.

5. (Amended) The multiple lumen access system of claim 4 further comprising a device lumen valve [adjacent the proximal end of the device lumen] to provide sealing of the device lumen when medical devices are both present and absent from the device lumen, wherein the device lumen valve is provided as part of the junction housing and is in fluid communication with the main channel.

7. (Amended) A multiple lumen access system of claim 6 wherein the main channel [continues] extends from the distal end of the junction housing [past the device channel to an opening in] and opens at the proximal end of the junction housing enabling introduction of fluids therethrough to the main channel.

10. (Amended) A multiple lumen access system according to claim 9 wherein the main channel [continues] extends from the distal end of the junction housing [past the device lumen to an opening in] and opens at the proximal end of the junction housing enabling introduction of fluids therethrough to the main channel.

17. (Amended) The multiple lumen access system of claim 1 wherein [at least] two auxiliary lumens are located within the outer tube of the multiple lumen access device.

21. (Amended) The multiple lumen access system of claim 1 wherein the auxiliary lumen has a maximum cross-section formed when the flexible wall is flexed away from the auxiliary lumen as far as possible, and the multiple lumen access device further includes an outlet for the auxiliary lumen formed in the outer tube, the outlet having an area that is greater than or equal to the maximum auxiliary lumen cross-section.

22. (Amended) The multiple lumen access system of claim 1 wherein [the flexible wall forms] there are two of the flexible walls that together form an inner tube within the outer tube.

23. (Amended) The multiple lumen access system of claim 22 wherein [there are two inner walls forming the inner tube,] the inner tube [having] has a distal end and a proximal end and an exterior surface and an interior surface, wherein the interior surface defines the device lumen, and wherein there are two of the auxiliary lumens [are] located between the exterior surface of the inner tube and an interior surface of the outer tube.

26. (Amended) The multiple lumen access system of claim 1 wherein the outer tube is made from a different material than the [at least one] flexible wall.

30. (Amended) A multiple lumen access system for use in providing an entry port into the human body for selectively introducing medical devices therethrough and for providing auxiliary access into the body, the system including a multiple lumen access device comprising:

a sheath defining within a device lumen having a distal end and a proximal end, wherein medical devices may be passed through the device lumen, and [at least one] an auxiliary lumen having a distal end and a proximal end;

a proximal junction housing made of a soft, flexible material having a proximal end and a distal end to which the proximal end of the sheath connects, the junction housing including a main channel in fluid communication with the device lumen and an auxiliary channel in fluid communication with the auxiliary lumen, the main channel and auxiliary channel diverging from each other [the outer tube] to be non-intersecting in the junction housing, the junction housing further defining a cavity on the proximal end in fluid communication with the main channel.

33. (Amended) A multiple lumen access system according to claim 31 further including a device channel in the junction housing formed at an angle with the main channel and terminating at an internal end in fluid communication with the main channel, the cavity being located at an outermost end of the device channel, the device lumen valve being positioned in the

cavity [at an outermost end of the device channel] so that medical devices may be inserted therethrough and enter the main channel at an angle.

37. (Amended) A multiple lumen access system according to claim 30 further including [at least one] a flexible wall located within the sheath and having a distal end and a proximal end and opposite sides, wherein one side of the wall partly defines the device lumen and the other side of the wall partly defines the auxiliary lumen, the wall being sufficiently flexible to be movable from a relaxed position, where[in] the device lumen at a particular location along its length has a first cross-sectional area, to multiple flexed positions, where[in] the device lumen at the particular location has corresponding multiple cross-sectional areas which are greater than or less than the first cross-sectional area of the device lumen, and wherein at the particular location the sheath has a cross-sectional area that remains substantially unchanged and any of the cross-sectional areas of the device lumen does not exceed [less than] the cross-sectional area of the sheath.

60. (Amended) A method for selectively introducing medical devices into a human body through a single entry port and for providing simultaneous auxiliary fluid access into the body, comprising:

providing a multiple lumen access device comprising:

an elongated body which has a distal end for introduction into the body and a proximal end, the elongated body having at a particular location along its length a cross-sectional area that remains substantially unchanged;

a device lumen through which medical devices may be passed defined within the elongated body, the device lumen having a distal end and a proximal end;

[at least one] an auxiliary lumen defined within the [outer tube] elongated body and separately from the device lumen, the auxiliary lumen having a distal end and a proximal end; and

[at least one] a flexible wall located within the [outer tube] elongated body having a distal end and a proximal end and opposite sides, wherein one side of the wall partly defines the device lumen and the other side of the wall partly defines the auxiliary lumen, the wall being sufficiently flexible to be movable from a first [relaxed] position, where[in] the device lumen at the particular location has a first cross-sectional area, to

multiple flexed positions, where[in] the device lumen at the particular location has corresponding multiple cross-sectional areas which are greater than or less than the first cross-sectional area of the device lumen, and wherein at the particular location any of the cross-sectional areas of the device lumen does not exceed [less than] the cross-sectional area of the [outer tube] elongated body;

introducing the multiple lumen access device into the body with the distal ends of the device lumen and the auxiliary lumen being positioned within a vasculature of the human body; and

flowing a medical solution through the auxiliary lumen into the vasculature in the absence of a device in the device lumen to move the flexible wall from the first [relaxed] position to one of the [a] flexed position.

62. (Amended) The method of claim 60 further comprising the step of providing the multiple lumen access device with [one or more] a fluid reservoir[s] connected to [one or more of] the proximal end[s] of the auxiliary lumen[s].

63. (Amended) The method of claim 60 further comprising the step of providing the multiple lumen access device with a device lumen valve [adjacent the proximal end of the device lumen] to provide sealing of the device lumen when medical devices are both present and absent from the device lumen.

64. (Amended) The method of claim [62] 63 further comprising the step of providing the multiple lumen access device with a junction housing having a proximal end and a distal end to which the proximal end of the elongated body connects, the junction housing including a main channel in fluid communication with the device lumen and [at least one] an auxiliary channel in fluid communication with the [at least one] auxiliary lumen, the main channel and auxiliary channel diverging from each other [the elongated body] to be non-intersecting in the junction housing.

67. (Amended) The method of claim 66 wherein the main channel [continues] extends from the distal end of the junction housing [past the device channel to an opening in] and opens

at the proximal end of the junction housing enabling introduction of fluids therethrough to the main channel.

70. (Amended) The method of claim 69 wherein the main channel [continues] extends from the distal end of the junction housing [past the device lumen to an opening in] and opens at the proximal end of the junction housing enabling introduction of fluids therethrough to the main channel.

75. (Amended) The method of claim 60 [71] wherein [at least] two auxiliary lumens are located within the elongated body of the multiple lumen access device.

76. (Amended) The method of claim 60 [75] wherein the distal ends of the two auxiliary lumens are located at different locations between the proximal and distal ends of the elongated body.

77. (Amended) The method of claim 60 [further comprising the steps of providing] wherein the multiple lumen access device [with] comprises an inner tube formed by two of the flexible walls located within the elongated body, the inner tube having a distal end and a proximal end, and the inner tube having an exterior surface and an interior surface wherein the interior surface defines the device lumen, and two auxiliary lumens located between the exterior surface of the inner tube and an interior surface of the elongated body.

79. (Amended) The method of claim 60 wherein the elongated body is made from a different material than the [at least one] flexible wall.

VERSION WITH MARKINGS TO SHOW CHANGES MADE

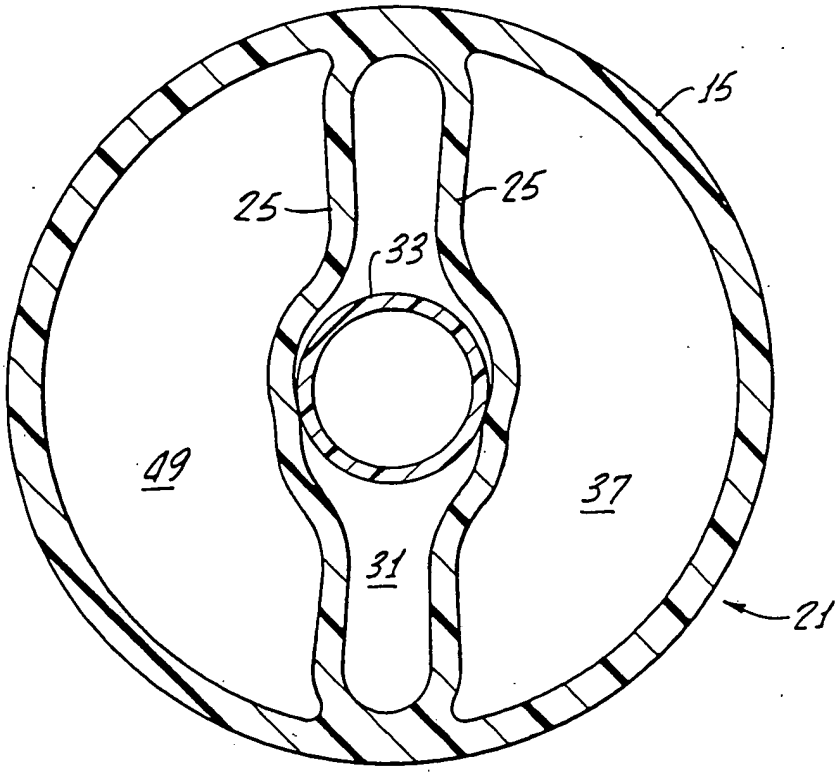
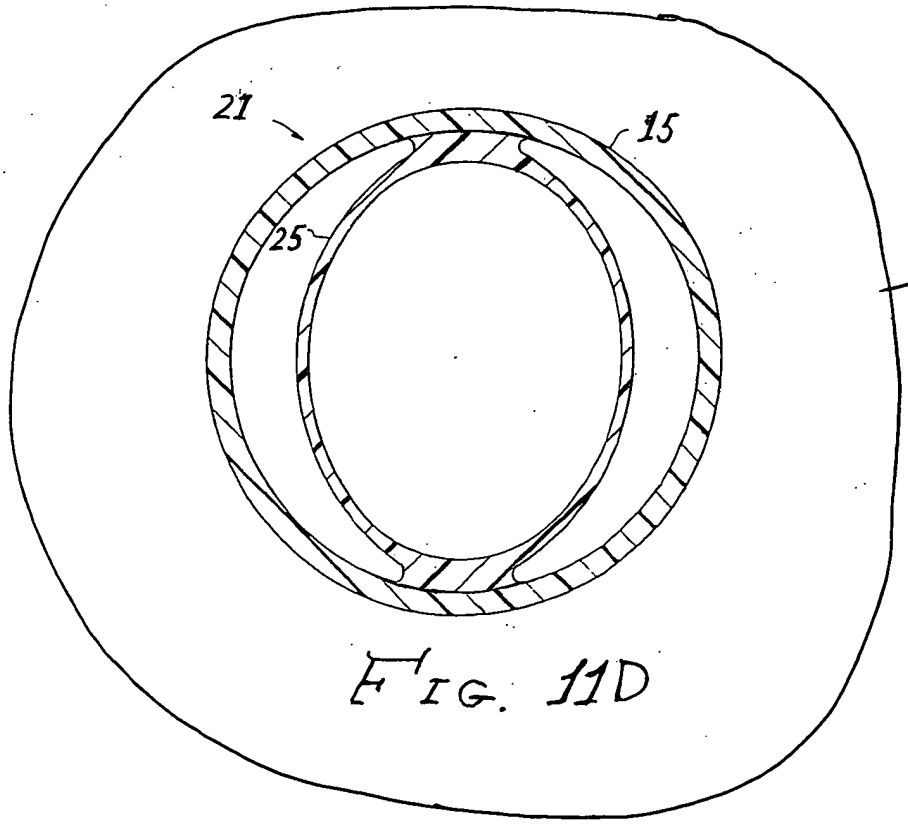


FIG. 11C



new Figure 11D

FIG. 11D

11/15/10